

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

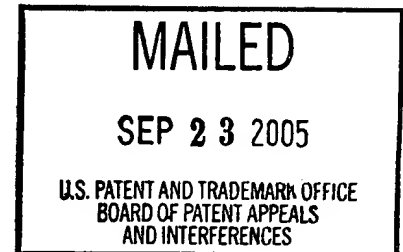
**UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Ex parte GHITA LANZENDORFER, and VOLKER SCHREINER

Appeal No. 2005-1913  
Application No. 09/744,506

ON BRIEF



Before ADAMS, MILLS and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 8, 9 and 18-23, which are all the claims pending in the application.

Claims 8, 21 and 22 are illustrative of the subject matter on appeal and are reproduced below:

8. A cosmetic and/or dermatological preparation comprising a bile acid or salt thereof in an amount of about 0.01% to about 0.5% by weight, based on the total weight of the preparation, wherein the salt is selected from the group consisting of alkali metal and alkaline earth metal salts, salts of mono- or divalent cations of elements from the transition groups, salts of mono- or divalent cations of elements from the lanthanides, salts of mono- or divalent cations of elements from

the actinides, salts of ammonium (-NH<sub>3</sub> [sic]), and salts of basic amino acids, wherein said bile acid is selected from the group consisting of dehydrocholic acid, lithocholic acid, cholic acid, glycocholic acid, taurolithocholic acid, ursodeoxycholic acid and taurocholic acid wherein the bile acid or salt thereof is in an encapsulated form selected from the group consisting of collagen matrices, cellulose encapsulations, gelatin, wax matrices, and liposomal encapsulations.

21. The preparation of claim 8, further comprising antioxidants in an amount of 1-10% by weight, based on the total weight of the preparation.
22. The preparation of claim 21, wherein said antioxidants are vitamin E and/or derivatives thereof in an amount of 0.001 – 10 % by weight, based on the total weight of the preparation.

The references relied upon by the examiner are:

Caserio et al. (Caserio)	4,664,910	May 12, 1987
Pittrof et al. <sup>1</sup> (Pittrof)	5,376,646	Dec. 27, 1994
Tisdale et al. (Tisdale)	6,103,246	Aug. 15, 2000

### GROUND OF REJECTION

Claims 8, 9 and 18-21 stand rejected under 35 U.S.C. § 103 as being unpatentable over Caserio in view of Tisdale.

Claims 22 and 23 stand rejected under 35 U.S.C. § 103 as being unpatentable over Caserio in view of Tisdale and Pittrof.

We reverse.

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<sup>1</sup> We note that the examiner did not include this reference in the "Prior Art of Record" section of the Answer. See Answer, section 9.

## DISCUSSION

### Claims 8, 9 and 18-21:

According to the examiner (Answer, page 3), “Caserio teaches a topical composition for skin or hair which comprises 0.1-20% of cholanic acid derivatives and a powder absorbent.” The examiner finds (id.), Caserio teaches “that lithocholic acid, deoxydycholic acid, and cholic acid are preferred cholanic acid derivatives.” The examiner finds (id.), Caserio teaches cosmetically acceptable carriers such as “[e]mollients, propellants, organic solvents, humectants, and thickeners....” In addition, the examiner finds (id.), Caserio teaches “to add antioxidants.”

Among other things, the examiner recognizes (Answer, page 4) that “Caserio fails to teach encapsulated forms.” The examiner relies on Tisdale to make up for this deficiency.

According to the examiner (id.), “Tisdale teaches that liposomes (encapsulated preparation forms) penetrate into the deep underlying [sic] layers of the skin where they deliver their active agents in a time-release action.” In addition, the examiner finds (id.), Tisdale “teaches that liposomes encapsulate ‘a portion of the solution’ in which the liposome is found.”

Based on this evidence the examiner concludes (Answer, bridging paragraph, pages 4-5).

[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Caserio invention by formulating the liquid composition in Caserio in the form of liposomes as taught by Tisdale because of the

expectation of successfully achieving a cosmetic composition with enhanced skin penetration and time-released action.

In response, appellants assert (Brief, page 5), “the [e]xaminer has merely found the elements [of their claimed invention] in isolated parts of the Caserio and Tisdale references without considering the prior art as a whole.” Appellants point out (Brief, page 4, emphasis removed), “Caserio teaches a cosmetic composition suitable for application to the skin as a powdered product to remove sebum and/or perspiration comprising a cholanic acid derivative and a powder absorbent.” In this regard, we find that Caserio teaches (column 4, lines 19-22, emphasis added), the composition provides a means whereby “active ingredients can be diluted, dispersed, conveyed to and distributed on the skin surface at an appropriate concentration.” Upon consideration of Caserio as a whole, we note that Caserio’s focus is on the application of the composition to the skin surface.

In contrast, as appellants point out (Brief, page 4, emphasis added), Tisdale teach “enhanced delivery of medically active components ... via increased skin penetration....”

Accordingly, we agree with appellants (Brief, page 6) that the question remains as to why it would have been prima facie obvious to a person of ordinary skill in the art, at the time of appellants’ claimed invention, to add the properties of enhanced skin penetrability and time release action, as taught by Tisdale, to the invention of Caserio? In response, the examiner asserts

(Answer, page 6),

the rejection is made from the perspectives of one of ordinary skill in the art, based on the objective teachings of the references of what would have been obvious to a skilled artisan at the time of the present invention. Tisdale teaches that liposomes are desired specifically because of the deep penetration of the cosmetic active ingredients to the underlying layers and skin so that the actives are delivered in a time-release action. The reference clearly teaches that the enhanced delivery of cosmetic actives to the skin layers is desired in cosmetic application, which is the examiner's cited reason to make the Caserio composition into a liposomal formulation.

While the examiner's assertion is less than clear, we understand the examiner's argument to be that a person of ordinary skill in the art would understand from Tisdale that liposomes are desirable because they can penetrate deep into the skin<sup>2</sup> and release their active agents in a time-release manner. Further, as we understand the examiner's assertions, since Caserio teaches active agents, one of ordinary skill in the art would have obviously wanted to incorporate them into liposomes so that they would be delivered deep into the skin, in a time-release manner.<sup>3</sup> In our opinion, not only is this assertion contrary to the law, it makes no sense in the context of the prior art relied upon.

As discussed above, as we understand it, Caserio's focus is on the application of a composition to the surface of the skin. Accordingly, it does not follow that simply because Caserio's composition contains active agents one of ordinary skill in the art would want to put this composition into a liposome for,

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<sup>2</sup> We recognize appellants' argument (Brief, page 4), that Tisdale attributes increased skin penetration to the presence of emu oil.

<sup>3</sup> See e.g., Answer, page 7, wherein the examiner states "[t]he ground of the rejection is that making [a] cholanic acid composition in to [sic] liposomal formulation as applicants have done

inter alia, deep penetration into the skin. Stated differently, it would appear to us that deep penetration into the skin would be contrary to Caserio's purpose of providing a composition whereby "active ingredients can be diluted, dispersed, conveyed to and distributed on the skin surface at an appropriate concentration." Caserio, column 4, lines 19-22.

As to the law, the initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In satisfying this initial burden, "it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." In re Wesslau, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965); see also In re Mercer, 515 F.2d 1161, 1165-66, 185 USPQ 774, 778 (CCPA 1975). Further, As set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. ... Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."

...  
Most if not all inventions arise from a combination of old elements. ... Thus, every element of a claimed invention may often be found in the prior art. ... However, identification in the prior art of each

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would have been obvious to a skilled artisan because then the composition would provide enhanced delivery of the active agent to the skin."

individual part claimed is insufficient to defeat patentability of the whole claimed invention. ... Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [Citations omitted].

In other words, "there still must be evidence that 'a skilled artisan, ... with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000). At best, the examiner has established that liposomes, and a composition comprising a cholanic acid derivative and a powder absorbent are known in the art. For the foregoing reasons, we find no suggestion to combine the disclosure of Caserio with that of Tisdale. In that regard, we note that prima facie obviousness based on a combination of references requires that the prior art provide "a reason, suggestion, or motivation to lead an inventor to combine those references." Pro-Mold and Tool Co. v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996).

[E]vidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. . . . The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular.

In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (citations omitted). The suggestion to combine prior art references must come from the cited references, not from the application's disclosure. See In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

For the foregoing reasons, it is our opinion that the examiner failed to meet her burden of establishing a prima facie case of obviousness. If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Therefore, we reverse the rejection of claims 8, 9 and 18-21 under 35 U.S.C. § 103 as being unpatentable over Caserio in view of Tisdale.

Claims 22 and 23:

The examiner relies on the combination of Caserio and Tisdale as set forth above. The examiner recognizes, however, that this combination “fail[s] to teach vitamin E.” Accordingly, the examiner relies on Pittrof to teach “cosmetic compositions comprising a cholanic acid and a lipid.” Answer, page 5. Based on this evidence the examiner concludes (id.),

[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding the tocopherol acetate as taught by Pittrof to the composition because the Caserio reference teaches that antioxidants are added to its composition, and Pittrof teaches tocopherol acetate as an antioxidant that can be combined with bile acid salt.

Appellant does not dispute that Pittrof teaches antioxidants. Thus, the issue before us is whether Pittrof makes up for the deficiency in the combination of Caserio and Tisdale as set forth above. In this regard, the examiner recognizes (Answer, page 5), Pittrof teaches a cosmetic composition comprising a cholanic acid and a lipid; and exemplifies a micelle solution comprising



tocopherol and sodium glycocholate.<sup>4</sup> However, as appellants point out (Brief, page 5), the lowest amount of a bile salt disclosed by Pittrof is 1.75% by weight, which is outside the range of bile salt set forth in appellants' claimed invention.

According to appellants (id.), this is significant because

Pittrof establishes a molar ration link between the lipid (lecithin) and the cholanin acid salt used in their invention of from about 0.1:1 to about 2:1 (see col. 1, lines 44-46). As micelles are well known to be concentration dependent (i.e. CMC – critical micelle concentration), Pittrof does not teach or suggest that micelles would have formed at the lower concentrations used by the appellants.

The examiner offers no response to this assertion. In this regard, we remind the examiner that “[w]hen prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over.” In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976). “If a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.” In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986). On this record, the examiner has not addressed appellants' rebuttal to the examiner's prima facie case. Here the examiner did not refute appellants' rebuttal argument.

Accordingly, we are compelled to find that Pittrof does not make up for the deficiencies in the combination of Caserio and Tisdale. Therefore, we reverse

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<sup>4</sup> According to Pittrof (column 1, lines 12-15), “[t]he preparations of the present invention have advantageous properties over conventional formulations including the improved penetration of the active substance and its improved distribution in the skin.” Thus, similar to Tisdale, it appears that Pittrof teaches penetration into the skin. Accordingly, for the reasons set forth above with regard to Tisdale, it is unclear why one would combine Pittrof with Caserio.

the rejection of claims 22 and 23 under 35 U.S.C. § 103 as being unpatentable over Caserio in view of Tisdale and Pittrof.

OTHER ISSUES

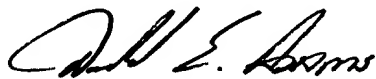
Appellants' Brief raises two issues that require further consideration by the examiner. Specifically, appellants assert:

1. "Claim 22 actually reads upon a broader range limitation that [sic] the claimed it is dependent upon...." Brief, page 3. Accordingly, appellants present what appears to be a proposed claim amendment.

2. claims 19 and 20 may be "duplicative in nature". Brief, page 3. Accordingly, it appears that appellants' intend to cancel claim 19.

Prior to any further action on the merits, we encourage the examiner to consider appellants' comments at page 3 of appellants' Brief, and take appropriate action.


REVERSED



Donald E. Adams  
Administrative Patent Judge



Demetra J. Mills  
Administrative Patent Judge



Lora M. Green  
Administrative Patent Judge

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NORRIS, MCLAUGHLIN & MARCUS, PA  
875 THIRD STREET  
18TH FLOOR  
NEW YORK NY 10022